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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/517,088	12/06/2004	**Jianming Chen**	6480P0010US	1147

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EXAMINER	
KISHORE, GOLLAMUDI S	

ART UNIT	PAPER NUMBER
1612	

MAIL DATE	DELIVERY MODE
06/23/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/517,088	CHEN ET AL.	
	Examiner	Art Unit	
	Gollamudi S. Kishore, Ph.D	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 April 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *7 and 9-22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *7 and 9-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The RCE dated 4-7-09 is acknowledged.

Claims included in the prosecution are 7 and 9-22.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 15-22 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. According to the newly added claim 15, water is added to the vitamin A Pro-liposome and only the mixing or vibrating is done before usage. According to page 7, lines 22-23 of the specification however, water is added before usage and the two components are then mixed or vibrated. This concept is not present in the specification as originally presented and therefore, deemed to be new matter.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 7 and 9-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicant recites poloxamer as one of the lipid components in the independent claims. It is unclear how one can form a liposome with this compound alone.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 7 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lee et al US 2003/0118616 in view of Modi (6,214,375) and Garrity (6,045,821).

Lee et al disclose liposomal formulations containing lecithin (0011, 0023), Retinol (Vitamin A), 1 % and sorbitol (2 %) (abstract and Table 4 on page 5). What is lacking in Lee et al is the use of saturated phospholipids such as DSPC or DPPC for the formation of liposomes. What is also lacking in Lee et al is the teaching of the use of sodium chloride.

Modi while disclosing liposomal formulations teaches that the use of substantially saturated phospholipids stabilize the liposomes as they are less prone to oxidation. The saturated lipids taught by Modi are DSPC and DPPC. One of the active agents taught

by Modi is a retinoid. Modi further teaches the use of polyvinyl pyrrolidone (abstract, col. 2, lines 21-46; col. 3, lines 3-11; col. 3, lines 65-67; col. 5, line 5).

Garrity while disclosing liposomal formulations teaches that sorbitol, mannitol and sodium chloride are cryoprotectants which aid the lyophilization and reconstitution processes (abstract, col. 12, lines 29-32; col. 9, lines 14-30).

The use of saturated phospholipids such as or DPPC or DSPC in Lee would have been obvious to one of ordinary skill in the art since Modi teaches that saturated phospholipids provide stability to liposomes. The use of sodium chloride instead of sorbitol in the liposomes of Lee et al with a reasonable expectation of success would have been obvious to one of ordinary skill in the art since Garrity teaches the equivalency between sorbitol and sodium chloride as cryoprotectants.

7. Claims 7 and 9-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Payne (4,744,989) by itself or in combination with Lee (US 2003/0118616) or Keller (6,610,322) or Cole (6,544,531) or Meybeck (5,034,228) by themselves or in combination.

Payne teaches proliposomal formulations and a method of preparation containing biologically active agents. The preparations contain carrier material such as mannitol and sodium chloride. The proliposomal preparations are made by dissolving the phospholipids in an organic solvent and coated on the material (mannitol or sodium chloride). The phospholipids include distearoylphosphatidylcholine, dipalmitoylphosphatidylcholine and dimyristoylphosphatidylcholine (abstract, col. 5, lines

54-67; col. 7, lines 14-44; examples and claims). Although Payne does not specifically teach vitamin A as the active agent, on col. 6, line 1 et seq., states that the biologically active compound employed in the invention may be any compound of biological interest. Therefore, it would have been obvious to one of ordinary skill in the art to use vitamin A as the biologically active agent in Payne with a reasonable expectation of success. One of ordinary skill in the art would be motivated to use vitamin A in Payne since the references of Lee, Keller, Cole and Meybeck each teach the routine use of vitamin A in either liposomes or proliposomal compositions.

Applicant's arguments have been fully considered, but are not found to be persuasive. Applicant's only argument is that the claims now recite the lipid ingredient to be one selected from the group consisting of Distearoylphosphatidylcholine, Dipalmitoyl Phosphatidyl Choline, Poloxamer, Dimyristoyl Phosphatidyl-choline, and mixtures thereof and that none of the prior art cited by the examiner discloses such a limitation. This argument is not persuasive since the references of Modi and Mehta disclose the claimed phospholipids.

The reference of Zou (5,902,604) which teaches preliposome formulations is cited as interest.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gollamudi S. Kishore, Ph.D whose telephone number is (571) 272-0598. The examiner can normally be reached on 6:30 AM- 4 PM, alternate Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Krass Frederick can be reached on (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Gollamudi S Kishore/
Primary Examiner, Art Unit 1612

GSK